UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,774	11/17/2005	Bernard Roizman	27373/38819A	2653

4743 7590 03/04/2008

MARSHALL, GERSTEIN & BORUN LLP
233 S. WACKER DRIVE, SUITE 6300
SEARS TOWER
CHICAGO, IL 60606

EXAMINER	
MOSHER, MARY	

ART UNIT	PAPER NUMBER
1648	

MAIL DATE	DELIVERY MODE
03/04/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/530,774	ROIZMAN ET AL.	
	Examiner	Art Unit	
	Mary E. Mosher, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 November 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4,6,8-16,19,20,22,23,26 and 35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,6,8-16,19,20,22,23,26 and 35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 April 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/25/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

Claims 15, 16, 22, 23, 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims require an "altered gD", but do not indicate the nature of the alteration. Therefore it is not clear what is encompassed by these claims.

Double Patenting

Claims 1, 2, 4, 6, 8-16, 19, 20, 22, 23, 26, 35 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-24, and 36 of copending Application No. 11/215636. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to using an altered gD fusion protein for receptor targeting.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 2, 4, 6, 8-16, 19, 20, 22, 23, 26, 35 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 7, 10, 15-21, 25-30 of copending Application No. 11/677026. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant broad claims encompass the narrower subject matter of the copending claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 4, 6, 8-10, 15, 16, 19, 20, 22, 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Glorioso et al WO 99/06583. Glorioso teaches attachment of a non-native ligand to an HSV surface glycoprotein, such as gB, gC, and/or gD, see page 7, for the purpose of redirecting binding, see page 2. Glorioso also teaches removing sequences from the HSV surface proteins that normally bind to cell surfaces, such as removing the heparin sulfate (HS) binding sites on gB or gC, or the HVEM-binding domain of gD, see pages 9-10. The suggested non-native ligands include

tumor-specific antigens present on cancerous cells (page 5). Fusion of the ligand to more than one protein is also suggested, see page 8. See also the claims.

Glorioso provides working examples of virus with altered gB and gC with reduced binding to sulfated proteoglycan (pages 13-14, 18-19), and further comprising a fusion of the altered gC with a heterologous ligand (page 21) and its specific affinity for the ligand's receptor (pages 22-23). Glorioso also provides working examples of virus with gB-ligand fusion protein (page 15) and its specific affinity for the ligand's receptor (page 22). Glorioso does not provide a working example using the gD fusion recited in the instant claims. However, one of ordinary skill in the art would have had a reasonable expectation of success in following the express suggestions in the reference to use gD as a fusion partner, and to reduce gD binding to the normal HVE receptor. Therefore, the invention as a whole is prima facie obvious, absent unexpected results.

Claims 11-13, 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Glorioso et al WO 99/06583 as applied to claims 1, 2, 4, 6, 8-10, 15, 16, 19, 20, 22, 23 above, and further in view of Debinski et al (Clinical Cancer Research 5: 985-990, 1999). These claims differ from Glorioso in requiring a ligand for a malignant giomal cell, specifically interleukin 13. However, Glorioso suggests using ligands for tumor-specific antigens present on cancerous cells. Debinski teaches that IL-13 is a ligand for a receptor specifically expressed on glioma brain tumors, and explicitly suggests its use as a target for delivery of cytotoxic or cytostatic therapies. Therefore, it would have been prima facie obvious to further modify Glorioso to use IL-13 as a glioma-specific ligand

for fusion to gD, with reasonable expectation of success. The invention as a whole is prima facie obvious, absent unexpected results.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Glorioso et al WO 99/06583 as applied to claims 1, 2, 4, 6, 8-10, 15, 16, 19, 20, 22, 23 above, and further in view of van Beusechem et al (Journal of Virology 76:2753-2762, March 2002). This claim differs from Glorioso in requiring fusion of a single-chain antibody as the ligand. However, van Beusechem teaches successful targeting of a recombinant virus to a tumor-specific receptor by use of single-chain antibodies. It would have been within the ordinary skill of the art to further modify Glorioso to use a single-chain antibody as a targeting ligand, with reasonable expectation of success. The invention as a whole is prima facie obvious, absent unexpected results.

Allowable Subject Matter

Claim 35 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims, provided that double patenting issues are also resolved.

The following is a statement of reasons for the indication of allowable subject matter: Glorioso et al WO 99/06583 and Laquerre et al (Journal of Virology 72:9683-9697, 1998) are cited as the closest prior art. Both Glorioso and Laquerre teach successful cell-specific binding of recombinant HSV with a gC/ligand fusion protein, leading to a reasonable of success for obtaining similar binding for HSV with other fusion proteins such as gD/ligand. However, Laquerre teaches that infection of the

targeted cell was abortive. This indicates less than a reasonable expectation of success for killing the target cell using the gD/ligand fusion protein to retarget the virus.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is 571-272-0906. The examiner can normally be reached on varying dates and times; please leave a message.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mary E Mosher, Ph.D./
Primary Examiner, Art Unit 1648

2/25/08